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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/23/2003

Cai-Zhong Jiang

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/669,824	<b>Applicant(s)</b> JIANG ET AL.	
	<b>Examiner</b> David H. Kruse	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,24-33,36-38 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 and 44 is/are allowed.
- 6) ☐ Claim(s) 22,24-33 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 21 January 2009 has been entered.
2. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments to the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

4. The disclosure is objected to because of the following informalities: At page 103, lines 14-16; the specification fails to comply with the Sequence Rules.

Appropriate correction is required.

### ***Allowable Subject Matter***

5. Claims 43 and 44 allowed. Applicants' arguments concerning claim 44 are persuasive (page 6, 4<sup>th</sup> paragraph of the Remarks).

### ***Claim Rejections - 35 USC § 112***

6. Claims 22, 24-33, 36-38, 41 and 42 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 20 August 2008. Applicant's arguments filed 21 January 2009 have been fully considered but they are not persuasive.

Applicants argue that the specification discloses a significant number of phylogenetically related sequence species that have conserved structure, the specification teaches how to identify other related sequence species using hybridization and percent identity, and the specification discloses how claimed sequences have conserved function related to the presence of two conserved domains, that is, structural elements, found within the sequences. Applicants argue that these sequences include, for example, soy G3456 (SEQ ID NO: 14) and *Arabidopsis* G2153 (SEQ ID NO: 6). Applicants argue that the specification predicts that "equivalogs of these sequences would function in a similar capacity" (page 39, line 31). Applicants argue that the specification discloses rice G3401 (SEQ ID NO: 38), listed as an ortholog in Table 5 on page 76 (page 7, 1<sup>st</sup> paragraph of the Remarks).

Applicants argue that the previously-submitted declaration of Dr. Ratcliffe shows that all of these sequences conferred increased tolerance to drought. Applicants argue that the specification discloses how G3456 (page 95, line 6) and G2153 (page 92, lines 24-26) confer increased biomass. G3401 also confers increased biomass (see U.S. patent application 12/077,535, filed 03-17-2008, page 167, the "G3401", rows showing

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"More tol. to drought\* and better recovery from drought treatment" and "Larger leaf size" (page 7, 2<sup>nd</sup> paragraph of the Remarks).

Applicants argue that the claimed sequences should include G3456, G2153, and G3401 (see percent identity analysis presented below). Applicants argue that the specification discloses three sequences that relate to the claimed subject matter and functions. Applicants argue that as these sequences are derived from very diverse species, they represent a considerable sampling of higher plants. Applicants argue that the USPTO, in its 1998 "Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 "Written Description" Requirement: A "representative number of species" requires that the species which are expressly described be representative of the entire genus. Thus, when there is substantial variation within the genus, it may require a description of the various species which reflect the variation within the genus. For example, a broadly drawn claim to a specific gene from ruminant mammals may require a representative species from cattle, buffalo, bison, goat, deer, antelope, camel, giraffe and llama." Applicants argue that as the level of expertise in the art has improved considerably since 1998, and since Applicants have provided functionally and structurally-related sequences from very diverse plant species, Applicants believe that they have met the written description requirements (page 7, 3<sup>rd</sup> and 4<sup>th</sup> paragraphs of the Remarks).

These arguments are not found to be persuasive. First, concerning Applicants' arguments concerning the phenotype of transformed plant, Applicants are arguing limitations not found in claims 22-31 and 42. Applicants state that the G2153 (SEQ ID

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NO: 6) and G3401 (SEQ ID NO: 38) are 65.6% and 60.3% identical respectively to SEQ ID NO: 14 (G3456) (pages 8 and 9 of the Remarks). The specification at pages 94-95 describes no structural and functional relatedness among these AT-hook transcription factors. Applicants' evidence of polypeptide sequence identity appears to be directed to species at the extremes of the claimed genus, and do not describe the variation within the genus. Applicants provide no evidence that a polynucleotide encoding either SEQ ID NO: 6 or 38 would bind to SEQ ID NO: 13 under the claimed stringency conditions. At claims 25, 30, 36 and 41, Applicants describe only one species that falls within the 90% identical genus. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424, 1433 (DC WNY 2003) which teaches knowing the "starting point" is not enough; that is little more than a research plan.

7. Claims 22 and 24-31 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a recombinant construct comprising a polynucleotide encoding SEQ ID NO: 14 and methods of using same, does not reasonably provide enablement for a recombinant construct comprising a polynucleotide encoding a polypeptide at least 60% or 90% identical to SEQ ID NO: 14 and methods of using same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants claim an expression vector, transgenic plant and method of making comprising a polynucleotide encoding an AT hook transcription factor polypeptide wherein the polynucleotide hybridizes to a nucleic acid sequence comprising SEQ ID

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NO: 13 under specific stringency conditions, or wherein the transcription factor polypeptide is at least 60% or 90% identical to SEQ ID NO: 14.

Applicants teach SEQ ID NOs 14, 6 and 38, which Applicants assert in the Responses filed on 20 January 2009 that these species fall within the genus encompassed by the claims.

Applicants do not sufficiently teach how to make and use the claimed genus because neither the AT hook domain nor the taught second conserved domain appear to teach a structure that adequately teaches a common function.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicants provide limited guidance on how to make and use the claimed genus of recombinant constructs as broadly claimed. It is recognized in the instant art that AT-hook (a type of HMG protein) proteins appear to play a role in transcription regulation by acting as accessory factors which influence the association of transcription factors with chromatin and act as transcription factor cofactors (Aravind *et al* 1998, Nucleic Acids Research 26(19): 4413-4421, page 4413, right column, 1<sup>st</sup> paragraph). The art teaches that AT-hook motifs seem to be auxiliary elements necessary for cooperation with other

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DNA-binding activities in the same or different proteins (Aravind *et al* 1998, page 4413, right column 2<sup>nd</sup> paragraph). Aravind *et al* 1998 teaches that the AT-hook is a short stretch of sequence similarity which makes it difficult to detect in conventional searches and discern scores which are statistically significant (page 4414, left column, 2<sup>nd</sup> paragraph). Aravind *et al* 1998 in Table 1 on pages 4415-4417 teach that AT-hook proteins have a wide variety of specific functions including enzymatic activity, positive and negative regulation functions, and chromatin structural functions. Hence, given the nature of the invention, the breadth of the claims and the amount of direction or guidance present, it would have required undue trial and error experimentation to make and use the invention as broadly claimed.

### ***Conclusion***

8. The claims as presently amended appear to be free of the prior art.
9. Claims 22, 24-33, 36-38, 41 and 42 remain rejected.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/  
Primary Examiner, Art Unit 1638  
30 March 2009